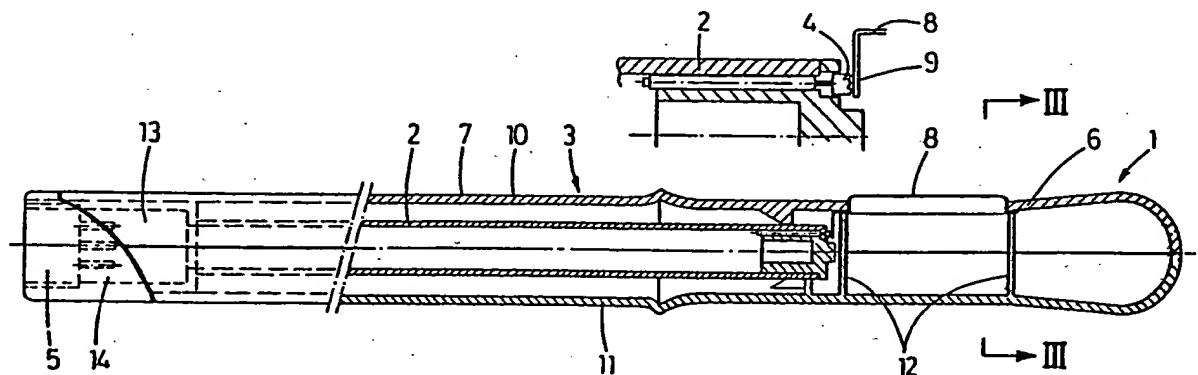




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61N 1/05, A61B 5/0492</p>	<p>A1</p>	<p>(11) International Publication Number: WO 90/12617</p> <p>(43) International Publication Date: 1 November 1990 (01.11.90)</p>
<p>(21) International Application Number: PCT/NL90/00054</p> <p>(22) International Filing Date: 24 April 1990 (24.04.90)</p> <p>(30) Priority data: 8901046 26 April 1989 (26.04.89) NL</p> <p>(71) Applicant (for all designated States except US): B.V. EN-RAF-NONIUS DELFT [NL/NL]; Röntgenweg 1, NL-2624 BD Delft (NL).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only) : VROEGOP, Willem, Frederik [NL/NL]; Giststraat 3, NL-2611 PT Delft (NL).</p> <p>(74) Agent: VAN DER BURG, Louis; B.V. Optische Industrie "De Oude Delft", P.O. Box 72, NL-2600 MD Delft (NL).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US.</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. In English translation (filed in Dutch).</p>

(54) Title: ELECTRODE FOR STIMULATING AND/OR DETECTING THE MUSCLE ACTIVITY OF MUSCLES OR MUSCLE GROUPS OF A PATIENT WHICH ARE ACCESSIBLE THROUGH A BODY ORIFICE



(57) Abstract

An electrode for stimulating and/or detecting the muscle activity of muscles or muscle groups of a patient. The electrode (1) comprises a carrier (2) and electrically conductive contacts (8). Via a cable the contacts (8) are connectable to a stimulation/detection device. The carrier (2) is provided with contact elements (4). An elongated throw-away sheath (10) of isolation material is detachably connectable to the carrier (2). When the sheath (10) is fixed in position the contacts (8) are on the outside of the sheath (10) and are connected to the contact elements (4).

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Electrode for stimulating and/or detecting the muscle activity of muscles or muscle groups of a patient which are accessible through a body orifice.

The invention relates to an electrode for stimulating and/or detecting the muscle activity of muscles or muscle groups of a patient which are accessible through a body orifice, provided with a carrier and at least two electrically conducting contacts which are connectable by means of a cable to a stimulation and/or detection apparatus.

A known electrode of this type is in the form of a vaginal electrode for stimulating and/or detecting the muscle activity of the pelvic floor muscles in women, in particular the sphincter of the urethra feminina. Incontinence problems in women can be treated in this way. Of course, with the use of such aids it is of great importance to practice good hygiene, in order to prevent infection between patients. In the case of the known electrode for this purpose essentially two possibilities have been used hitherto. A first possibility is to disinfect or, if necessary, sterilize the electrode after each treatment. This is relatively laborious and time-consuming. The second possibility is to give each patient her own electrode, but this calls for a high investment in electrodes. Besides, in this case extensive administration is required, and cleansing of the electrodes is still necessary.

The object of the invention is to provide an electrode of the type mentioned in the preamble, in which the above-mentioned disadvantages are eliminated in a simple, yet effective manner.

For this purpose, the electrode of the type mentioned in the preamble is characterized according to the invention in that the carrier is provided with

contact elements and in that a disposable, elongated sheath of insulating material is detachably connectable to the carrier, while the contacts are situated on the outside of the sheath and are connected to the contact elements when the sheath is fitted on the carrier.

In this way an electrode made up of two parts is obtained, the part coming into contact with the body orifice being disposable after use, so that disinfection or sterilization are no longer necessary. The part which is disposed of after use comprises a simple sheath of insulating material which can be mass-produced at very low cost. The other part, onto which the sheath is pushed, can be made sturdy, and is suitable for use a number of times.

According to a preferred embodiment, the sheath is composed of a rigid plastic material and comprises a part which is adapted in shape to the body orifice, and to which a handle is connected, the contacts being fixed in the sheath and each having a contact lip in the interior of the sheath, which contact lips are in contact with the contact elements when the sheath is fitted on the carrier. An electrode which is easy to handle in practice is obtained in this way.

According to an alternative embodiment, the carrier is made elongated and is provided with a part which is of a shape adapted to the body orifice and has a handle connecting thereto, while the sheath is made of a thin, flexible material.

The invention is explained in greater detail below with reference to the drawing, in which a number of examples of embodiments are shown schematically.

Fig. 1 is a side view, partially produced in cross-section, of a first embodiment of the electrode according to the invention.

Fig. 2 is a top view of the electrode according to

Fig. 1.

Fig. 3 is a section along the line III-III from Fig. 1.

Fig. 4 is a schematically shown longitudinal section of a second embodiment of the electrode according to the invention.

Fig. 5 shows a detail of Fig. 4 on a larger scale.

Figs. 1 - 3 show an electrode 1 for stimulating and/or detecting muscle activity of muscles or muscle groups of a patient which are accessible through a body orifice. This electrode 1 is provided with a carrier core 2, in this case in the form of an elongated element, and a sheath 3 which is detachably connectable to the carrier core 2. The carrier core 2 is made of, for example, rigid plastic material and bears on the one end, illustrated in the enlarged detail in Fig. 1, four contact elements 4 which are supported in a resilient manner in the axial direction in the end of the carrier core 2, and only one of which can be seen in Fig. 1. The contact elements 4 are connected by conductors (not shown) to a connector 5, which is situated on the other end of the carrier core 2. A cable for connecting the electrode 1 to a stimulation and/or detection apparatus can be connected to the connector 5.

The sheath 3 is made of a rigid plastic material and comprises a part 6 which is adapted in shape to the body orifice, in this case the vagina, and to which a handle 7 is connected, by means of which the electrode is easy to handle and easy to insert into the body orifice. As shown in the cross-section of Fig. 3, four contacts 8 are fitted in the part 6 of the sheath 3, said contacts in this example projecting relative to the outside surface of the sheath 3, so that a good contact with the skin is ensured. The contacts 8 each have at their end a connecting lip 9, these lips projecting

radially into the sheath 3 and being pressed against the contact elements 4 when the sheath 3 is slid onto the carrier core 2.

As an alternative, the carrier core 2 can be made considerably shorter, in which case the contacts 8 of the sheath 3 are connected, for example by means of conductors incorporated in the sheath, to connecting lips which are fitted nearer to the open end of the sheath. Of course, differently designed contact elements and connecting lips are also possible.

The sheath 3 is composed of two elongated shell halves 10 and 11, of which the top shell half 10 shown in Fig. 1 has recesses for the contacts 8. The other shell half 11 has two clamping plates 12 which in the assembled state of the sheath 3 fix the contacts 8 in the recesses of the shell half 10.

The carrier core 2 has at the end of the connector 5 a shut-off part 13 of larger diameter which is accommodated in a close fit in the handle 7 of the sheath 3. This shut-off part 13 bears a casing 14 which runs from the side situated opposite the contacts 8 approximately in a circular arc shape to the side where the contacts 8 are situated to a groove 15 formed in the casing 14. The corresponding end of the sheath 3 has a matching shape, by means of which the sliding of the sheath 3 onto the carrier core 2 produces correct positioning of the carrier core 2 and the sheath 3 relative to each other and the contact elements 4 always come to rest against the connecting lips 9 of the contacts 8.

Figs. 4 and 5 show an alternative embodiment of the invention. In this case the electrode has an elongated carrier 16 which is provided with a part 17 with a shape which is adapted to the body orifice and a handle 18 connecting thereto. In this case use is made of a sheath

19 of a thin flexible material, which in Fig. 4 for the sake of clarity is shown greatly exaggerated at a great distance from the carrier 16, but in practice can lie in a more close-fitting manner around said carrier 16.

5 Recesses 20 for receiving loose contacts 21 are formed in the part 17 of the carrier 16; four of said recesses are again present, and only one can be seen in Fig. 4. Contact elements 22, which are slidable to and fro in the axial direction by means of a button 23, are fitted
10 in the carrier 16. These contact elements 22 are in turn connected, in a manner not shown, to a connector 24 fitted at one end of the carrier 16.

Before use, a sheath 19 is fitted over the carrier 16 and four contacts 21 are pressed into the recesses 20
15 of the carrier 16. Each contact 21 here has a contact end 25 which pierces through the sheath and is locked on the contact element 22. The sheath 19 is held fast in a sealing manner between the contact 21 and the recesses 20 of the carrier 16, so that the carrier 16 remains
20 insulated from the environment. After use, the contacts 21 can be released again by withdrawing the contact elements 22 with the button 23.

It is pointed out that the contacts 8, 21 in the embodiments described are strip-shaped and are fitted in
25 the axial direction of the electrode. This ensures that even without accurate positioning of the electrode in the body cavity good positioning relative to the sphincters is achieved. It is, however, also possible to use annular or partially annular electrodes.

30 The shape adapted to the body orifice also means that the electrode remains in place despite any muscle contractions.

Although the above describes an electrode for use in the vagina for stimulating or detecting muscle
35 activity of the sphincter of the urethra feminina, the

electrode according to the invention with a suitable shaping can also be used for treatment of the sphincter ani. Put in more general terms, the electrode is suitable for stimulating and/or detecting muscles or muscle groups which are accessible through a body orifice such as, for example, the pelvic floor muscles of a woman.

It can be seen from the above that an electrode is provided with a carrier 2, 16 which is suitable for multiple use, and a sheath 3, 19 which is discarded with the contacts 8, 21 after use. These parts are very simple in design and can be mass-produced at low cost. This means that the electrode described in both embodiments is very suitable for the treatment of patients with incontinence problems, in which case, on the one hand, stimulation of the muscle activity can take place and, on the other, the muscle activity of the muscles or muscle groups, such as the pelvic floor muscles, can be detected. After use, the disposable part 3, 8 or 19, 21 can be thrown away, so that no disinfection or sterilization of the electrode is necessary.

The invention is not limited to the examples of embodiments described above, which can be modified in various ways within the scope of the invention.

Claims

1. Electrode for stimulating and/or detecting the muscle activity of muscles or muscle groups of a patient which are accessible through a body orifice, provided with a carrier and at least two electrically conducting contacts which are connectable by means of a cable to a stimulation and/or detection apparatus, characterized in that the carrier is provided with contact elements and in that a disposable, elongated sheath of insulating material is detachably connectable to the carrier, while the contacts are situated on the outside of the sheath and are connected to the contact elements when the sheath is fitted on the carrier.

2. Electrode according to Claim 1, characterized in that the sheath is composed of a rigid plastic material and comprises a part which is adapted in shape to the body orifice, and to which a handle is connected, the contacts being fixed in the sheath and each having a contact lip in the interior of the sheath, which contact lips are in contact with the contact elements when the sheath is fitted on the carrier.

3. Electrode according to Claim 2, characterized in that the carrier and the sheath are provided with complementary positioning elements.

4. Electrode according to Claim 2 or 3, characterized in that the sheath is composed of two elongated shell halves, one shell half of which has recesses in which the contacts are placed, while the other shell half has clamping plates which are positioned at the recesses and which in the assembled state fix the contacts in the recesses.

5. Electrode according to Claim 2, 3 or 4, characterized in that the connecting lips project radially into the sheath, and in that the contact

elements are supported resiliently in the axial direction at one end of the carrier.

6. Electrode according to Claim 1, characterized in that the carrier is made elongated and is provided with a part with a shape adapted to the body orifice and with a handle connecting thereto, while the sheath is made of a thin, flexible material.

7. Electrode according to Claim 6, characterized in that the contacts are designed as loose contacts which can be fixed, with clamping of the flexible sheath, on the carrier for bringing about the connection to the contact elements.

8. Electrode according to Claim 7, characterized in that the loose contacts each have a contact end which pierces the sheath during fitting on the carrier, the carrier having recesses for receiving the contacts, and the sheath being held fast between the contacts and the recesses.

9. Electrode according to any of the preceding claims, characterized in that at the end situated opposite the end to be inserted into the body orifice the carrier is provided with a connector to which the cable can be connected.

10. Electrode according to any of the preceding claims, characterized in that the contacts project relative to the outer surface of the sheath.

11. Sheath, intended for use with an electrode according to any of the preceding claims.

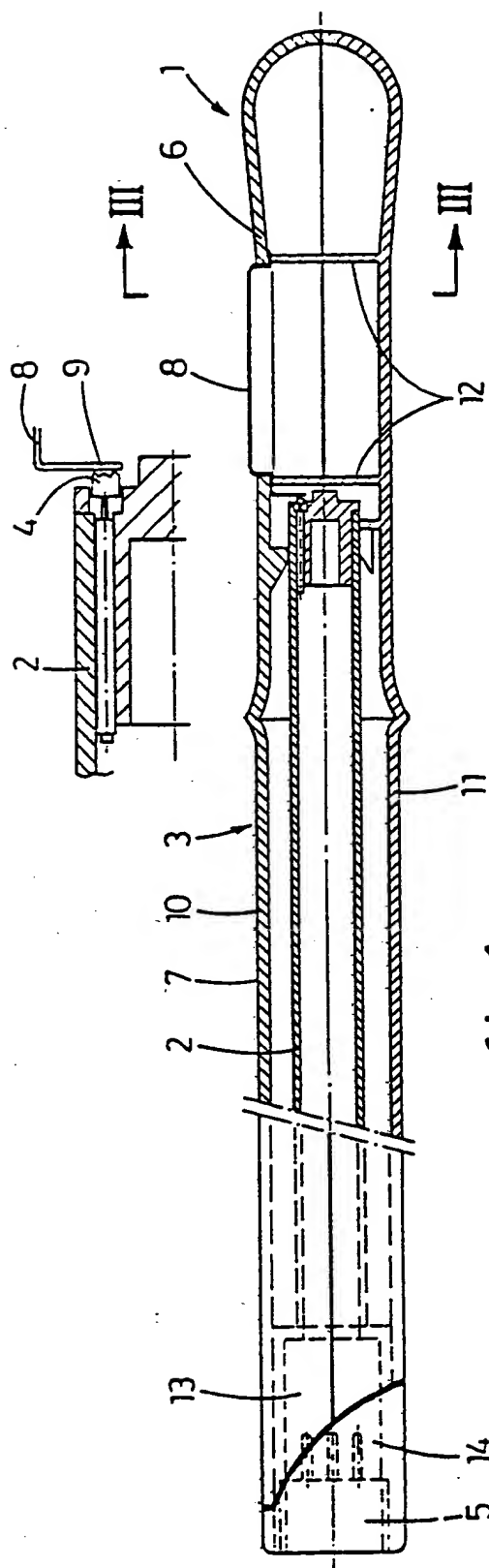


fig.1

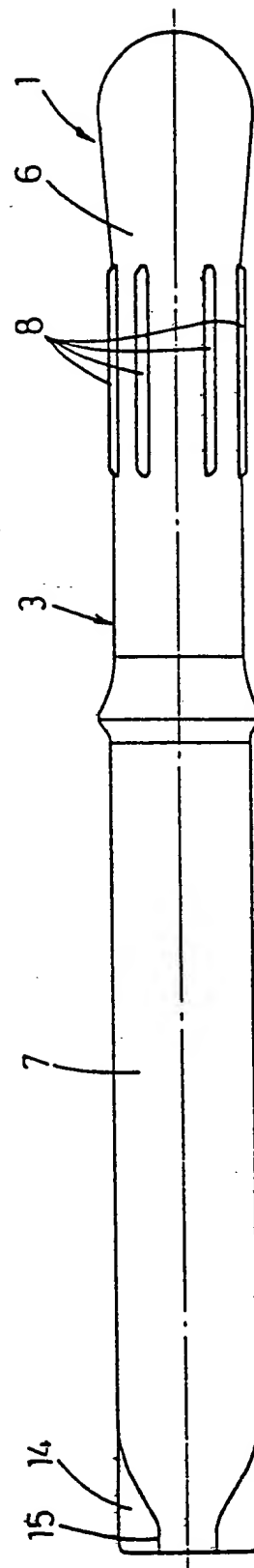


fig.2

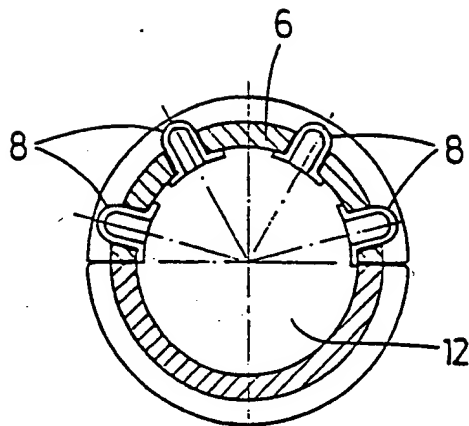


fig.3

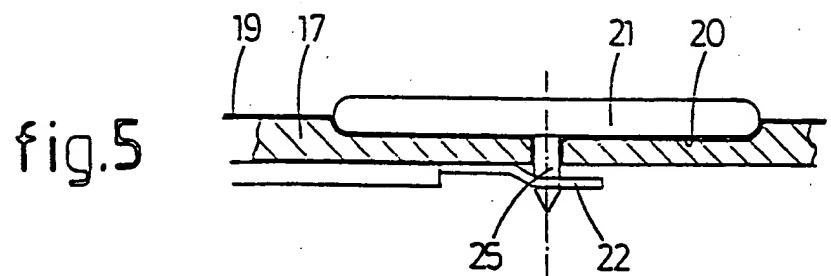


fig.5

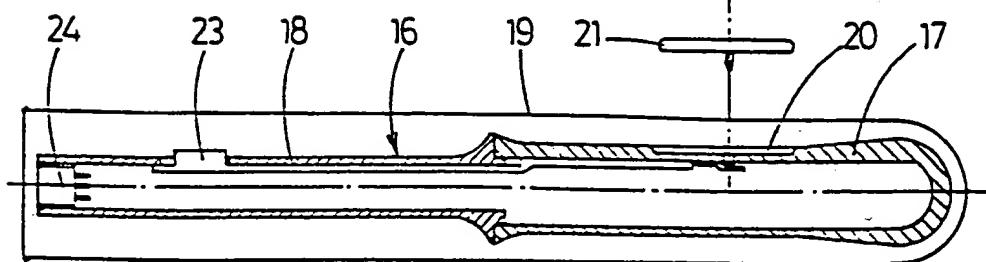
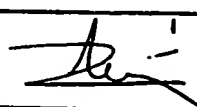


fig.4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 90/00054

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61N1/05 ; A61B5/0492		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
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Int.Cl. 5	A61N ; A61B	
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III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	EP,A,263466 (MAURER) 13 April 1988 see page 3, column 3, line 4 - column 4, line 17; figure 1 ---	1, 6, 11
A	US,A,2085644 (FERCIOT) 29 June 1937 see page 1, right-hand column, line 13 - page 2, left-hand column, line 27 ---	1, 9, 11
A	US,A,3920003 (ASH) 18 November 1975 see column 4, line 6 - column 5, line 55 ---	1, 2, 5, 11
A	US,A,4819650 (GOLDSTEIN) 11 April 1989 see column 3, line 32 - column 4, line 32 ---	1, 3
A	US,A,4124028 (GALLO) 07 November 1978 see column 4, lines 8 - 44 ---	1, 2, 4
<p>⁹ Special categories of cited documents : ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"R" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
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ANNEX TO THE INTERNATIONAL SEARCH REPORT

ON INTERNATIONAL PATENT APPLICATION NO. PCT/NL 90/00054

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-263466	13-04-88	US-A- 4785828 US-A- 4873996	22-11-88 17-10-89
US-A-2085644		None	
US-A-3920003	18-11-75	None	
US-A-4819650	11-04-89	None	
US-A-4124028	07-11-78	AU-B- 520249 AU-A- 3477078 GB-A- 1593115 JP-A- 53130176	21-01-82 11-10-79 15-07-81 13-11-78

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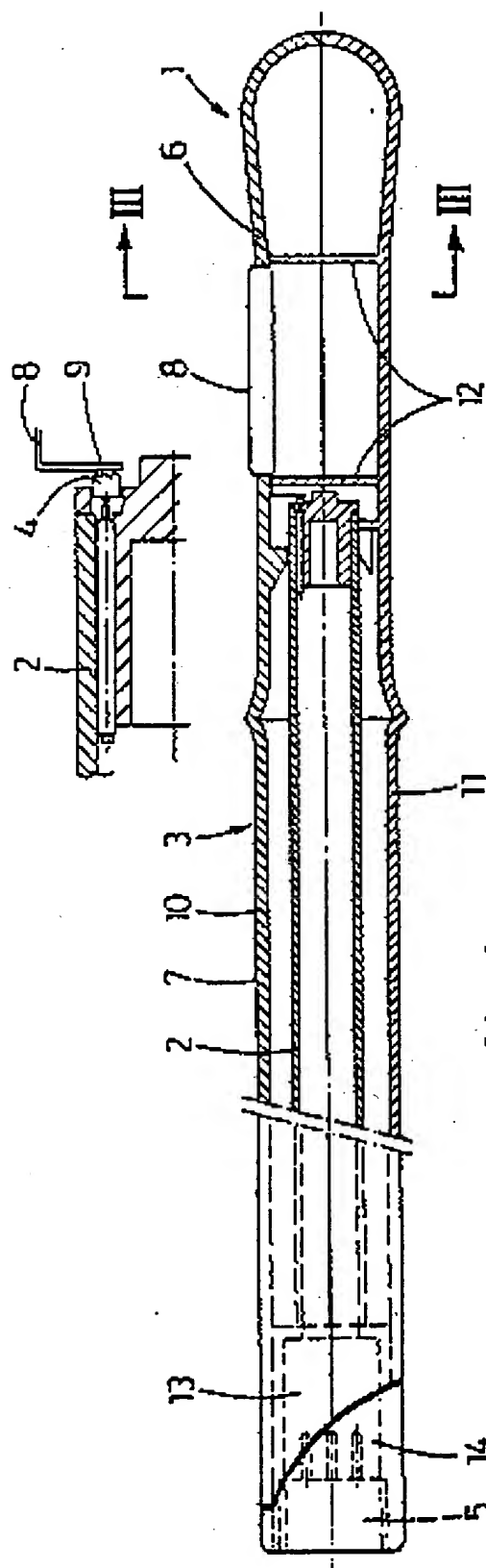


fig.1

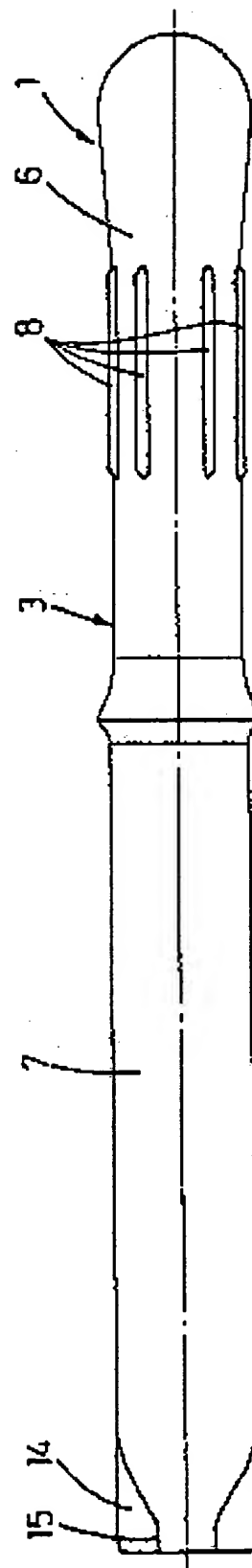


fig.2

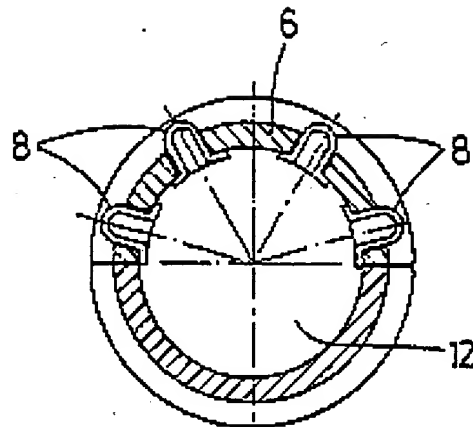


fig.3

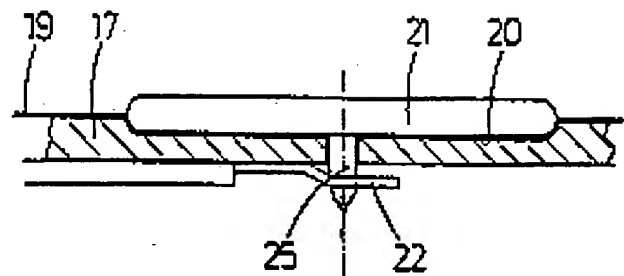


fig.5

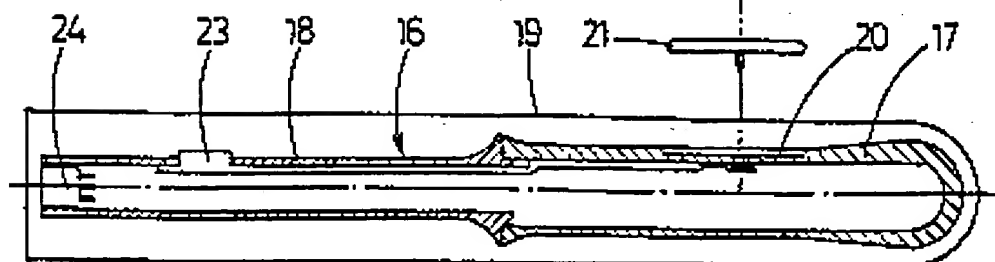


fig.4